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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,969	04/21/2000	Donald G. Wallace	17067-002040	6560

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EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/553,969

Applicant(s)

WALLACE ET AL.

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 19-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 19-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of associate power of attorney filed 9-16-02, request for extension of time (granted) and amendment filed 11-13-02 is acknowledged. Claims 19-33 have been added. Claims 1 and 19-33 are pending.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1 and 19-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Berg et al (4,837,285; hereafter '285).

'285 discloses resorbable wound compositions comprising gel particles to that are sufficiently open to stimulate cellular ingrowth and are applied with a syringe (abstract; C 2, L 49-64; C 3, L 42-C 4, L 5; C 4, L 55-56; C 5, L 10-68; examples; claims). See MPEP 2113 for rejection of Product-by-process claims under 35 U.S.C. 102. In the instant case, the product of the instant claim is a hydrogel in particle form and the product of '285 is in bead form. There does not appear to be any difference between a bead and a particle and the Patent Office is not equipped to

Art Unit: 1615

manufacture products by the various processes put before it and then obtain prior art products and make physical comparisons therewith. '285 also discloses that the size of the beads is within the instant range, swell within the instant range, and degrade *in vivo* in less than one year.

Response to Arguments

3. Applicant's arguments filed 11-13-02 have been fully considered but they are not persuasive. Applicant argues that the beads of '285 are not in the form of a fragmented hydrogel since the beads are formed of stiff and incompressible fibers which define interior pores connected by internal channels. This argument is not found persuasive. Applicant's description of '285 appears to be somewhat misinterpreted in that Applicant asserts that the beads are "stiff and incompressible." Column 2, lines 20-33 disclose that the beads are "sufficiently stiff and non-compressible to fill and protect a wound." This does not mean that the beads are completely stiff and do not compress at all. It only means that they maintain their form. Also, the instant specification defines collagen as one of the polymers for the instant hydrogels and it is the position of the examiner that this is a property of the polymer itself. Furthermore, Example 10 of '285 mixes the beads with a solution that hydrates the beads.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al (4,837,285; hereafter '285).

'285 discloses resorbable wound compositions comprising gel particles to that are sufficiently open to stimulate cellular ingrowth and are applied with a syringe (abstract; C 2, L 49-64; C 3, L 42-C 4, L 5; C 4, L 55-56; C 5, L 10-68; examples; claims). See MPEP 2113 for rejection of Product-by-process claims under 35 U.S.C. 102. In the instant case, the product of the instant claim is a hydrogel in particle form resulting from mechanical disruption and the product of '285 is in bead form resulting from spray drying. Furthermore, page 10, lines 4-27 of the instant specification admits that there is no criticality between mechanical disruption and spray drying. The motivation for choosing between the two being a matter of convenience in that one may be more easily accomplished whether by accessibility or price. Therefore, the burden is shifted to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. '285 also teaches that the size of the beads is within the instant range, swell within the instant range, and degrade *in vivo* in less than one year.

Response to Arguments

6. Applicant's arguments filed 11-13-02 have been fully considered but they are not persuasive. Applicant argues that the beads of '285 are not in the form of a fragmented hydrogel since the beads are formed of stiff and incompressible fibers which define interior pores connected by internal channels. This argument is not found persuasive.

Art Unit: 1615

Applicant's description of '285 appears to be somewhat misinterpreted in that Applicant asserts that the beads are "stiff and incompressible." Column 2, lines 20-33 disclose that the beads are "sufficiently stiff and non-compressible to fill and protect a wound." This does not mean that the beads are completely stiff and do not compress at all. It only means that they maintain their form. Also, the instant specification defines collagen as one of the polymers for the instant hydrogels and it is the position of the examiner that this is a property of the polymer itself. Furthermore, Example 10 of '285 mixes the beads with a solution that hydrates the beads.

7. Claims 26-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al (4,837,285; hereafter '285) in view of Hull et al (EP 0 493 387, ;hereafter '387).

'285 is relied upon for all that it teaches as stated previously. '285 also teaches inclusion of a non-biological polymer and a polysaccharide and inclusion of pharmaceutically active agents, but does not specifically teach inclusion of a clotting agent such as thrombin.

'387 teaches inclusion of thrombin in wound treatment formulations.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include thrombin in the formulation of '285 with the motivation of imparting the ability to stop bleeding upon the formulation of '285.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Application/Control Number: 09/553,969

Page 7

Art Unit: 1615

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw

January 24, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600